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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

GRUN, JAMES LESLIE

ART UNIT

PAPER NUMBER

1641

DATE MAILED: 05/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/052,788	<b>Applicant(s)</b> GERSHWIN ET AL.	
	<b>Examiner</b> James L. Grun	<b>Art Unit</b> 1641	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 March 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 10-52 is/are pending in the application.  
     4a) Of the above claim(s) 13,16,25 and 28-46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 10-12,14,15,17-24,26,27 and 47-52 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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The amendment filed 23 March 2006 is acknowledged and has been entered. Claims 48-52 are newly added. Claims 1-9 have been cancelled. Claims 10-52 remain in the case. Of these, claims 29-46 have been withdrawn from further consideration as being drawn to a non-elected invention and claims 13, 16, 25, and 28 have been withdrawn from further consideration as being drawn to a non-elected species. Accordingly, claims 10-12, 14, 15, 17-24, 26, 27, and 47-52 are under active examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to provide an adequate written description of the invention, and failing to adequately teach how to make and/or use the invention, i.e. failing to provide an enabling disclosure.

The specification is objected to and claims 10-12, 14, 17-24, 26, and 47-52 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons of record that the specification contains subject matter which was not described in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. As set forth, applicant teaches only antibodies elicited to a single species, SEQ ID NO: 5, which function for the specific identification of native equine IgE in a sample as intended by applicant. Applicant's algorithms did not provide any predictable success for functional species other than SEQ ID NO: 5. Unguided unpredictable experimentation to determine other functional species would be undue experimentation.

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Applicant's arguments filed 23 March 2006 have been fully considered but they are not deemed to be persuasive. Notwithstanding applicant's assertions to the contrary, the examiner, in the prior Office action, indicated that only antibodies binding to or elicited with the isolated peptide comprising the amino acid sequence set forth in SEQ ID NO: 5, but not the full breadth of the claims, meet the enablement provision of 35 U.S.C. §112, first paragraph.

Claims 22-24, 26, 27, 50, and 51 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 22-24, 26, and 27, improper Markush language is now used to claim the members of the group. The alternatives "selected from...or" or "selected from the group consisting of...and" are acceptable.

Claims 50 and 51 improperly depend from claim 10 because a composition, not the antibody, is claimed.

Applicant's arguments filed 23 March 2006 have been fully considered but they are not deemed to be persuasive. Notwithstanding applicant's assertions to the contrary, applicant's amendments have not obviated rejections under this statute for the reasons set forth above.

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

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Claims 48 and 50 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. There is no indication that the product as claimed is isolated and no claimed degree of purity for the product that would indicate "the hand of man". Thus, the product as claimed is considered a product of nature, which is non-statutory subject matter.

Claims 10-12, 14, 15, 17, 18, 20, 22-24, 26, 27, 47-50, and 52 are rejected under 35 U.S.C. § 102(b) as being anticipated by Halliwell et al. (Curr. Eye Res. 4: 1023, 1985) in light of Watson et al. (Vet. Allergy Clin. Immunol. 5: 135, 1997) or the instant disclosure for reasons of record.

Applicant's arguments filed 23 March 2006 have been fully considered but they are not deemed to be persuasive. Applicant urges that Halliwell et al. do not disclose the sequence of the immunogen used, or the epitope specificities of the elicited antibodies. This is not found persuasive for the reasons of record because, inherently, the polyclonal population contained antibodies binding to any and every of the immunogenic epitopes in the protein, the protein having the sequences as disclosed in light of the extrinsic evidence of Watson et al. (1997) or the instant disclosure. The examiner would note that the antibodies specific for the various peptides are not claimed as isolated, purified, or otherwise separated from other antibodies in a polyclonal antibody population as provided by the reference. Further, the Patent and Trademark Office does not have the facilities and resources to provide the *factual* evidence needed in order to establish that there is a difference, in the first place, between the reagents of the prior art and those instantly disclosed and, that if there is such a difference, that such a difference would have been

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considered unexpected, i.e. unobvious, by one of ordinary skill in the art. The burden is upon applicant to present such factual evidence. See e.g. In re Best (195 USPQ 430 (CCPA 1977)) or Ex parte Phillips (28 USPQ2d 1302 (BPAI 1993)).

Claims 10-12, 14, 15, 17-24, 26, 27, 47, and 50-52 are rejected under 35 U.S.C. § 103 (a) as being unpatentable over the combined teachings of Marti et al., Griot-Wenk et al., Watson et al., and Lerner et al. for reasons of record.

Applicant's arguments filed 23 March 2006 have been fully considered but they are not deemed to be persuasive.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In this regard, applicant urges that Marti et al. or Griot-Wenk et al. do not teach the sequences as disclosed in Watson et al. or in the instant specification. This is not found persuasive because Watson et al. teach the sequences as instantly disclosed. Further, notwithstanding applicant's implication to the contrary, and absent evidence to the contrary, the minimal epitope required for antibody binding is 5-6 amino acid residues not the entire sequences of the 15-mers as instantly disclosed, thus the noted sequence differences of peptides having partial identity may not affect antibody binding to the identical parts of the sequences.

Applicant urges that, although apparently following the teachings of Lerner et al., Watson et al. failed to generate antibodies binding to native equine IgE. This is not found persuasive for

a number of reasons. Firstly, in response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., binding to native equine IgE) are not specifically recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Secondly, the reference of Watson et al. teaches that only some of the predicted multiple antigenic sites were tried and this does not serve to teach away from the use of others of the predicted sites. Moreover, Griot-Wenk et al. teach the immunogenicity of the equine IgE CH2 domain and the elicitation of anti-equine IgE antibodies thereto.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR REPLY TO THIS FINAL ACTION IS SET TO EXPIRE **THREE MONTHS** FROM THE MAILING DATE OF THIS ACTION. IN THE EVENT A FIRST REPLY IS FILED WITHIN **TWO MONTHS** OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE **THREE-MONTH** SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR REPLY EXPIRE LATER THAN **SIX MONTHS** FROM THE MAILING DATE OF THIS FINAL ACTION.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to James L. Grun, Ph.D., whose telephone number is (571) 272-0821. The examiner can normally be reached on weekdays from 9 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, SPE, can be contacted at (571) 272-0823.

The phone number for official facsimile transmitted communications to TC 1600, Group 1640, is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application, or requests to supply missing elements from Office communications, should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



James L. Grun, Ph.D.

May 11, 2006



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05/12/06